

K024141

MAR 06 2003

510(K) SUMMARY

Submitter of 510(k): SB LUCIUS, INC.
9778 Katella Ave. Ste. 205, Anaheim, CA 92804
Phone: (714) 530-2814, Fax : (714) 530-3448,

Contact person: Dae Kyu Chang
Phone: (714) 530-2814
Fax: (714) 530-3448
E-mail: Gatorkr@yahoo.co.kr

Date of Summary: Dec 15, 2002

Trade name: NEO 76
Common: Dental casting alloy
Classification name: Gold based alloys and precious metal alloys for clinical use
Product code: EJT
Classification: Class II

Legally marketed device: ARGENCO 77

510(k) number: K893385

SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS

Test methods applied: as in ANSI/ADA 5 and ISO 9693

Comparison of composition:

COMPOSITION (WEIGHT %)

Device Name	Au	Pt	Pd	Ag	CU	Zn	IR/In
ARGENCO 77	77.0	1.0	-	13.0	8.45	<1.0	<1.0
NEO 76	76.0	1.42	0.5	14.0	7.0	1.0	0.08

Comparison of physical and mechanical properties:

Alloy	Melting Point Range (°F)	Hardness (Vickers)	Yield Strength (MPa)	Elongation (%)	Density (g/cm3)
ARGENCO 77	1,695 -1,760	105	214	36	15.9
NEO 76	1,784-1,840	148	270	48	16.1

Discussion:

Since the composition of the legally marketed alloy and the new device is very similar, it may be assumed that the biological compatibility of the alloys is also very similar.

Conclusion:

The main elements and their concentration are almost identical. NEO 76 is an inlay, onlay, crown and bridge alloy. This device is dependable 76% gold alloy with a high gold appearance. NEO 76 is excellent for inlays, three-quarter crowns, long and short-span bridges. NEO 76 is substantially equivalent to ARGENCO 77 and the minor differences between them do not affect safety or effectiveness.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAR 06 2003

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Dae-Kyu Chang
SB LUCIUS, Incorporated
9778 Katella Avenue, Suite 205
Anaheim, California 92804

Re: K024141

Trade/Device Name: NEO 76

Regulation Number: 872.3060

Regulation Name: Gold-based Alloys and Precious Metal Alloys for Clinical Use

Regulatory Class: II

Product Code: EJT

Dated: December 15, 2003

Received: December 16, 2003

Dear Mr. Chang

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
<http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SB LUCIUS, INC.

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Phone: (714) 530-2814,
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INDICATIONS FOR USE

510(K) Number : K024141

Device Name(s) : NEO 76

NEO 76 is intended for manufacturing

- Inlay / Onlays
- Crowns
- Short span bridges
- Long span bridges
- Removable partials

(PLEASE DO NOT WRITE BELOW THIS LINE CONTINUE ON ANOTHER PAGE IF NEEDED)

CONCURRENCE OF CHRD, OFFICE OF DEVICE EVALUATION(OED)

Susan Riner

(Division Sign-Off)

Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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